

Claims

1. A diagnostic method for detecting and identifying bacterial species causing infections from a clinical sample, characterized by
 - 5 a) amplifying DNA isolated from said clinical sample using a mixture of DNA primers that comprises sequences which hybridize with the sequences that originate from conserved regions of *rpoB* genes encoding DNA directed RNA polymerase [EC:2.7.7.6] subunit B of bacterial species causing infections, said sequences comprising sequences identified by SEQ. ID. NR: 20 and 21
 - 10 b) contacting the amplified DNA with a desired combination of oligonucleotide probe sequences that hybridize under normal hybridization conditions with hyper-variable regions situated near said conserved regions of *rpoB* genes encoding DNA directed RNA polymerase [EC:2.7.7.6] subunit B of bacterial species causing said infections, said sequences being bacterial species-specific under said hybridization conditions, and
 - 15 c) detecting the formation of a possible hybridization complex.
2. The diagnostic method according to claim 1, characterized in that said infections causing bacterial species are bacterial species that cause human disease, particularly respiratory tract infections and/or ear, nose and throat diseases.
- 20 3. The diagnostic method according to claim 1 or 2, characterized in that said hyper-variable region is the hyper-variable region of the gene encoding the *rpoB* protein of a bacterial species selected from *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Legionella pneumophila*, *Corynebacterium diphtheriae*, *Mycoplasma pneumoniae*, *Escherichia coli*, *Moraxella catarrhalis* and *Neisseria gonorrhoeae*.
- 25 4. The diagnostic method according to any one of claims 1 to 3, characterized in that the length of oligonucleotide probe sequences used in step b) is 15 – 30, more preferably 19 – 30, and most preferably 19 – 26 nucleic acids and are optionally labeled.
- 30 5. The diagnostic method according to any one of claims 1 to 4, characterized in that said combination of oligonucleotide probe sequences comprises all or a portion of the sequences identified by SEQ. ID. NR: 1 to 19, and/or reverse and/or complementary sequences thereof, or functional frag-

ments thereof and preferably it comprises all the sequences identified by SEQ. ID. NR: 1 to 19,

6. The diagnostic method according to claim 5 or 6, characterized in that said combination of oligonucleotide probe sequences is attached onto a 5 solid support, preferably onto treated glass.

7. The diagnostic method according to claim 1, characterized in that the DNA isolated from the clinical sample in step a) is amplified using the polymerase chain reaction (PCR) and that the DNA amplified in step b) is contacted with bacterial species-specific oligonucleotide probes attached onto a 10 solid support.

8. The diagnostic method according to claim 7, characterized in that suitably labeled nucleotides are used in the amplification of DNA isolated from a clinical sample in step a) to generate a detectable target strand and that the amplified and optionally labeled target DNA in step b) is contacted with a solid 15 support, on which all bacterial species-specific oligonucleotide probes identified by SEQ. ID. NR: 1 to 19 and/or reverse and/or complementary sequences thereof have been attached.

9. The diagnostic method according to claim 8, characterized in that the amplified and optionally labeled target DNA in step b) is contacted with a 20 solid support, preferably treated glass, on which specific oligonucleotide probe sequences detecting one specified bacterial species or a few specified bacterial species causing infections have been attached, said sequences being selected from sequences shown in Table 3 and/or complementary sequences thereof.

25 10. The diagnostic method according to any one of claims 1 to 9, characterized in that the microarray technology is used in step c).

11. A DNA primer mixture, characterized by comprising sequences that hybridize with sequences of the conserved regions of *rpoB* genes encoding DNA directed RNA polymerase [EC:2.7.7.6] subunit B of bacterial species 30 that cause infections, said mixture comprising sequences identified by SEQ. ID. NR: 20 and 21 and/or complementary sequences thereof or functional fragments thereof.

35 12. An oligonucleotide sequence useful in the diagnosis of infection causing bacterial species, characterized in that it hybridizes under normal hybridization conditions with a sequence of a hyper-variable region that is bacterial species-specific and is situated near the conserved regions of *rpoB* genes

encoding DNA directed RNA polymerase [EC:2.7.7.6] subunit B of bacterial species causing said infections, said oligonucleotide sequence being bacterial species-specific and said oligonucleotide sequence comprising one of the sequences identified by SEQ ID. NR: 1 to 19 and/or reverse or complementary 5 sequences thereof functional fragments thereof.

13. The combination of oligonucleotide probe sequences useful in the diagnosis of infection causing bacterial species, characterized by comprising any combination of the sequences identified by SEQ. ID. NR: 1 to 19 and/or reverse or complementary sequences thereof or functional fragments 10 thereof.

14. The combination of oligonucleotide probes according to claim 13, characterized by comprising all of the sequences identified with SEQ. ID. NR: 1 to 19.

15. The use of the combination of oligonucleotide probes according 15 to claim 13 or 14 for the detection, identification, or classification of disease causing bacterial species.

16. A diagnostic kit for use in the diagnosis of infection-causing bacteria, especially those causing respiratory tract infections, characterized by comprising

20 a) a DNA primer mixture comprising sequences that hybridize with sequences of the conserved regions of *rpoB* genes encoding DNA directed RNA polymerase [EC:2.7.7.6] subunit B of bacterial species causing infections, especially bacterial species that cause respiratory tract infections, said mixture comprising sequences identified with SEQ. ID. NR: 20 and 21 and/or reversed 25 or complementary sequences thereof or functional fragments thereof,

b) a combination of bacterial species-specific oligonucleotide probe sequences, optionally attached on a solid support, comprising any combination of the sequences identified with SEQ. ID. NR: 1 to 19 and/or reverse or complementary sequences thereof or functional fragments thereof,

30 c) positive and optionally negative control probe sequences, and optionally

d) reagents required in the amplification, hybridization, purification, washing, and/or detection steps.